NOTICE OF VIOLATION

Froedtert Memorial Lutheran Hospital
Milwaukee, Wisconsin

License Nos. 48-04193-01;
48-04193-03
Docket Nos. 030-03444;
030-11119

During an NRC inspection conducted on September 23-26, 1996, with continued NRC in-office review through November 12, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

License Nos. 48-04193-01 and 48-04193-03:

1. 10 CFR 35.32(a)(1) requires, in part, that the licensee establish and maintain a quality management program which must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any teletherapy or brachytherapy radiation dose.

   10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation and containing information including, for any teletherapy dose: (1) the total dose; (2) dose per fraction; (3) treatment site; and (4) overall treatment period. Additionally, written directives for any high-dose-rate remote afterloading brachytherapy dose must include: (1) the radioisotope; (2) treatment site; and (3) total dose.

   Contrary to the above, on several occasions as of September 25, 1996, the licensee failed to prepare written directives that included all of the required information prior to administering teletherapy and high-dose-rate remote afterloading brachytherapy doses. Specifically, the licensee administered teletherapy doses and the written directives did not include the overall treatment period. Additionally, the licensee administered high-dose-rate remote afterloading brachytherapy doses and the written directives did not include the total dose.

   This is a Severity Level IV violation (Supplement VI).

License No. 48-04193-01:

2. Condition 27 of License No. 48-04193-01 requires, in part, that prior to initiation of a treatment program, and subsequent to each source exchange using the remote afterloading brachytherapy device, radiation surveys be performed in all areas adjacent to the treatment room with the source in the "irradiation" position to evaluate compliance with 10 CFR 20 limits.

Contrary to the above, on several occasions as of September 1996, the radiation surveys performed subsequent to source changes did not include all areas adjacent to the treatment room. Specifically, the surveys conducted on July 29, 1996, May 13, 1996, January 3, 1996, November 8, 1995, and July 27, 1995 included less than all accessible adjacent areas.

This is a Severity Level IV violation (Supplement VI).

3. 10 CFR 35.315(a)(4) requires in part that, for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, a licensee promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10 CFR Part 20.

   Contrary to the above, on several occasions as of September 25, 1996, the licensee administered dosages of iodine-131 to patients for radiopharmaceutical therapy which required hospitalization for compliance with 10 CFR 35.75, and the licensee did not measure the dose rates in contiguous restricted and unrestricted areas. Specifically, the licensee failed to perform radiation surveys in all areas lateral and below rooms 542S and 541S, rooms used to hospitalize patients for compliance with 10 CFR 35.75.

   This is a Severity Level IV violation (Supplement VI).

4. 10 CFR 35.415(a)(4) requires in part that, for each patient receiving brachytherapy and hospitalized for compliance with 10 CFR 35.75, a licensee promptly after implant, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10 CFR Part 20.

   Contrary to the above, on several occasions as of September 25, 1996, the licensee implanted sealed sources in patients for brachytherapy which required hospitalization for compliance with 10 CFR 35.75, and the licensee did not measure the dose rates in contiguous restricted and unrestricted areas. Specifically, the licensee failed to perform radiation surveys in all areas lateral and below rooms 542S and 541S, rooms used to hospitalize patients for compliance with 10 CFR 35.75.

   This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Froedtert Memorial Lutheran Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a

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"Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the basis for your claim of withholding (e.g., explain why the disclosure of information will create unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.790(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Dated at Lisle, Illinois
this 27th day of November 1996